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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,029	03/16/2001	Martin C. Barnardo	1181-251	5589
6449	7590	03/03/2006	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			COUNTS, GARY W	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/809,029

Applicant(s)

BARNARDO ET AL.

Examiner

Gary W. Counts

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-17, 20, 22-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-17, 20, 22-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

The amendment filed December 14, 2005 is acknowledged and has been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-7, 9-17, 20, and 22-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-7, 9-17, 20, and 22-28 are drawn to recombinant MHC molecule that binds only one antibody, that is recombinant molecule that presents a unique epitope of a naturally occurring MHC allele and binds to only one allele specific anti-MCH antibody. Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F. 3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure,

formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Id.* At 1567, 43 USPQ2d at 1405. The court also stated that

a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore, cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

.Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. " A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-

Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (FED. Cir. 2002). The Enzo court adopted the standard that “the written description requirement can be met by ‘show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics...i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.” Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of the recombinant MHC molecule, per Lilly by structurally describing a representative number of recombinant MHC molecules or by describing “structural features common to the members of the genus, which features constitute a substantial portion of the genus.” Alternatively, per Enzo, the specification can show that the claimed invention is complete “by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.”

In this case, the specification does not describe the recombinant MHC molecules in a manner that satisfies either the Lilly or Enzo standards. The

Art Unit: 1641

specification does not provide the complete structure or any recombinant MHC molecule, nor does the specification provide any partial structure of such recombinant MHC molecule, nor any physical or chemical characteristics of the recombinant MHC molecule nor any functional characteristics coupled with a known or disclosed correlation between structure and function other than recombinant HLA-A2 and HLA-B8. Although the specification discloses recombinant HLA-A2 and HLA-B8, this does not provide a description of any and all recombinant MHC molecules that binds only one antibody, that is recombinant MHC molecule that presents a unique epitope of a naturally occurring MHC allele and binds to only one allele specific anti-MCH antibody that would satisfy the standard set out in Enzo.

The specification also fails to describe the recombinant MHC molecules that presents a unique epitope of a naturally occurring MHC allele and binds to only one allele specific anti-MCH antibody by the test set out in Lilly. The specification describes only recombinant HLA-A2 and HLA-B8 molecules. Therefore, it necessarily fails to describe a "representative number" of such species. In addition the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus.". Thus, the specification does not provide an adequate written description of the recombinant MHC molecules that presents a unique epitope of a naturally occurring MHC allele and binds to only one allele specific anti-MCH antibody that is required to practice the claimed invention. Therefore, since it fails to describe the recombinant MHC molecules that presents a

unique epitope of a naturally occurring MHC allele and binds to only one allele specific, it also fails to adequately describe the claimed methods.

3. Claims 1-7, 9-17, 20 and 22-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for recombinant HLA-A2 and recombinant HLA-B8 molecules, does not reasonably provide enablement for any and all recombinant molecules. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. The factors that must be considered in determining undue experimentation are set forth in *In re Wands* USPTQ2d 14000. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The instant claims are directed to recombinant MHC molecules that present a unique epitope of a naturally occurring MHC allele and binds to only one allele specific anti-MHC antibody.

One cannot extrapolate the teaching of the specification to the enablement of the claims because other than recombinant HLA-A2 and HLA-B8 molecules, the specification does not teach any and all recombinant MHC molecules that will function

Art Unit: 1641

as claimed. The identification of these recombinant MHC molecules do not predictably enable the broadly claimed invention because other than this teaching, the specification provides no information as to structures common to the any and all recombinant MHC molecules that allow one of skill to predictably make the claimed recombinant MHC molecules based on a structure/function correlation. The specification on page 8, lines 18-34 discloses that the sequence of naturally occurring MHC molecules may be modified providing areas which make up at least one unique epitopic site (which may be provided by one or more of the components of the MHC molecule), particularly regions of variability which allow presentation of at least one unique epitopic region which typifies a particular MHC allele and which results in the production of specific MHC antibodies directed to that region re maintained such that the aid specific antibodies are still capable of binding to that region. As will be appreciated this requires maintenance of not only residues at the epitopic site, but also key skeletal residues to achieve correct folding of the MHC molecule to form the epitopic site. Further, as disclosed in the specification it was surprisingly found that individual recombinant HLA molecules could be used for specifically detecting anti-HLA antibodies. The specification teaches that methods of identifying of anti-HLA antibodies are known in the art. Given the above, it appears that Applicant is suggesting random experimentation in order to find the recombinant MHC molecules that will function as claimed. Random experimentation is undue. Further, although one would expect screening assays would be useful to identify recombinant MHC molecules that present a unique epitope of a naturally occurring MHC allele and binds to only one allele specific anti-MHC antibody, it is

Art Unit: 1641

particularly noted that screening assays do not enable the claimed invention because the court found in (*Rochester v. Searle*, 358 F.3d 916, Fed Cir., 2004) that screening assays are not sufficient to enable an invention because they are merely a wish or plan for obtaining the claimed invention.

Response to Arguments

4. Applicant's arguments with respect to claims 1-7, 9-17, 20, 22-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. No claims are allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 1641


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts
Examiner
Art Unit 1641
February 22, 2006



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02/24/06